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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,315	10/29/2001	Robert V. Farese JR.	UCAL-105CIP2	1732

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/040,315

**Applicant(s)**

FARESE ET AL.

**Examiner**

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-17, 19-21 and 66 is/are rejected.
- 7) ☐ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### **DETAILED ACTION**

Applicant's amendment of claims 15, 17, 18 and the addition of new claim 66 in the paper of 5/25/2005, is acknowledged. Claims 1-22 are still at issue and are present for examination.

Applicants' arguments filed on 5/25/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 1-14 and 22-65 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed.

### ***Claim Objections***

Claims 15 and 18 are objected to because of the following informalities:

Newly amended claim 15 recites "... diacylglycerol O-acyltransfreases (DGAT) modulatory activity..." Acyltransfrease should not be plural.

Claim 18 is dependent on rejected claim 15.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a screening assay for determining a candidate agent's DGAT modulatory activity, comprising contacting a DGAT polypeptide having the amino acid sequence of SEQ ID NO: 5, with said candidate agent and detecting any change in activity of said DGAT polypeptide compared to a control to determine said candidate agent's DGAT modulatory activity, does not reasonably provide enablement for any screening assay for determining a candidate agent's DGAT modulatory activity, comprising contacting a DGAT polypeptide, having the a mere 90% amino acid sequence identity to the amino acid sequence of SEQ ID NO: 6, with said candidate agent and detecting any change in activity of said DGAT polypeptide compared to a control to determine said candidate agent's DGAT modulatory activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was made in the previous office action as it applied to previous claims 15-21. In response to this rejection applicants amended claims 15, 17 and 18 and traversed the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that applicants specification describes a number of species of DGAT polypeptides, including human DGAT (SEQ ID NO: 6), mouse DGAT (SEQ ID NO: 7) and a plant DGAT (SEQ ID NO: 10). Applicants

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further submit that applicants teach how to determine whether an agent modulates DGAT activity as well as working examples. Thus applicants conclude given this guidance combined with the skill in the art those skilled in the art could carry out the claimed screening assay without undue experimentation.

Applicants complete argument has been considered, however, found nonpersuasive on the basis that while applicants have provided three additional species of DGAT polypeptides that may be used in the claimed screening assay as well as direction in determining whether an agent modulates DGAT activity, this amount of guidance is insufficient to enable the claimed genus of screening assays that encompass the use of any DGAT polypeptide having a mere 90% amino acid sequence identity to SEQ ID NO: 6. While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, the variants encompassed by applicants claims (i.e., 90% identical to the DGAT polypeptide of SEQ ID NO: 6) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the near infinite number of variants have the necessary property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does

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not establish: (A) regions of the protein structure of DGAT which may be modified without effecting DGAT activity; (B) the general tolerance of DGAT polypeptides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a DGAT with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the DGAT activity necessary to practice the claimed methods and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would continue to require undue experimentation for one skilled in the art to arrive at the majority of those methods of use of those DGAT polypeptide of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any screening assay for determining a candidate agent's DGAT modulatory activity, comprising contacting any DGAT polypeptide, having a mere 90% sequence identity to SEQ ID NO: 6, with said candidate agent and detecting any change in activity of said DGAT polypeptide compared to a control to determine said candidate agent's DGAT modulatory activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

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determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

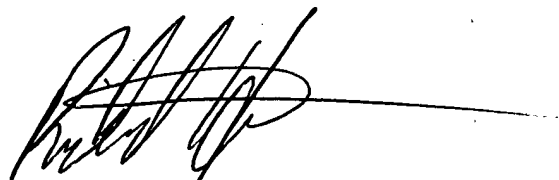
The rejection of claims 15, 16 and 19 under 35 U.S.C. 102(a) as being anticipated by Tabatan et al. (Phytochemistry, Vol 46, No. 4, October 1997, pp 683-687, See IDS), is hereby withdrawn based on applicants amendment of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', followed by a long horizontal line extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

Rgh  
12/28/2004